

Application No. 10/035,861
Amdt. Dated June 17, 2004
Reply to Office Action of February 17, 2004

REMARKS/ARGUMENTS

1. Remarks on the Amendments

Claims 1 and 14 have been amended to more specifically define Applicant's claimed invention.

Antecedent basis of the amendment of Claims 1 and 14 can be found on page 15, second paragraph of the specification. Applicant respectfully submits no new matter has been introduced by the amendments.

Claims 25-29 have been withdrawn without prejudice.

2. Response to the Double Patenting Rejections

(1) Claims 1, 2, 6 and 14-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 5-6 of US 6,174,733.

(2) Claims 3-5 and 16-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 5-6 of US 6,174,733 in view of Lee et al (US 5,672,475).

(3) Claims 1, 2, 6 and 14-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 14-22 of US 6,337,214.

(4) Claims 3-5 and 16-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 14-22 of US 6,337,214 733 in view of Lee et al (US 5,672,475).

These rejections are respectfully traversed.

Obviousness-type double patenting is a judicial creation designed to preclude improper timewise extension of the patent rights by proscribing the issuance of claims in a second patent that are not "patently distinct" from the claims of a first

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patent. In *re Braat*, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991).

Thus the principal inquiry is "whether the claimed invention in the application for the second patent would have been obvious from the subject matter of the claims in the first patent, in light of the prior art." In *re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Determination of obviousness-type double patenting essentially involves the determination of unobviousness under 35 USC § 103, except that the first patent disclosure is not applicable as "prior art." In *re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Importantly, there must be some clear evidence to establish why the invention's variation in the second application would have been obvious, with that evidence properly qualifiable as "prior art." For example, "even if obviousness of the variation is predicated on the level of skill in the art, prior art evidence is needed to show what the level of skill was." In *re Kaplan*, 789 F.2d at 1580, 229 USPQ at 683.

In the present application, Claims 1, 2, 6, 14 and 15 are patentably distinct over Claims 5 and 6 of US patent No 6,174,733 and further patentably distinct over Claims 14-22 of US patent No 6,337,214.

More specifically, Claims 1, 2, 6, 14 and 15 of the present claimed invention relate to a method of detection of multiple test materials by having at least two capture materials on the same snare, binding multiple test materials on the same snare, adding different probes sequentially on the same test snare, and detecting different test materials sequentially on the same test snare.

Claims 5 and 6 of US patent No 6,174,733 teach a method of detecting at least two DNA materials by binding each material to a specific snare, and detecting different DNA materials on different snares. Therefore, Claims 5 and 6 of US patent No 6,174,733 fail to teach or imply Claims 1, 2, 6, 14 and 15 of the present claimed invention, instead they teach away from the present claimed invention.

Claim 14 of US patent No 6,337,214 teaches a method of detecting more than one DNA sequence by binding different DNA sequences to different snares and detecting different sequences (i.e., target and control) on different snares.

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Furthermore, Claims 21-22 of US patent No 6,337,214 teach that there are more than one capture DNA sequences on one single snare, and that probes and labels are different for detecting different sequences on the single snare. However, Claims 14-22 of US patent No 6,337,214 do not teach a method of detecting more than one test materials by sequentially binding different probes to the same snare, and sequentially detecting different test materials on the same snare. More specifically, they do not teach the present claimed method of binding the first probe and detecting the first test material, and binding the second probe after the first detection, then detecting the second test material. Furthermore, recognizing the difficulty of detecting different material on the same snare, Claim 22 of US patent No 6,337,214 teaches that the labels are different so that different DNA sequences can be detected on one single snare. With the present claimed invention defined by independent Claims 1 and 14, such a technical constrain is eliminated.

Therefore, Applicant maintains that Claims 1, 2, 6, 14 and 15 of the present claimed invention are not obvious in view of Claims 5 and 6 of US patent No 6,174,733, or Claims 14-22 of US patent No 6,337,214.

Accordingly, Applicants request withdrawal of the rejection of Claims 1, 2, 6, 14 and 15 under the judicially created doctrine of obviousness-type double patenting.

With regard to Claims 3-5 and 16-17, these claims are dependent claims of Claims 1 and 14, respectively, which further define that the chemical labels are chemiluminescence labels, more specifically acridinium dye.

Since Claims 3-5 and 16-17 are dependent upon independent Claims 1 and 14, under the principles of 35 U.S.C. §112, 4th paragraph, all of the limitations of each independent claim are recited in its respective dependent claims. As described above, the independent Claims 1 and 14 of the present claimed invention are patentably distinct over Claims 5 and 6 of US patent No 6,174,733 and further patentably distinct over Claims 14-22 of US patent No 6,337,214, as such Claims 3-5 and 16-17 are submitted not obvious variations of Claims 5 and 6 of US patent No 6,174,733 or Claims 14-22 of US patent No 6,337,214.

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Moreover, Lee et al (US 5,672,475) merely teach using acridinium dye as a label, but fail to teach Applicant's claimed method.

One ordinary skilled in the art would not be motivated to combine the prior art teaching as suggested by the Examiner, because such combination would not obtain Applicant's present claimed invention of the method of sequentially binding different probes, and sequentially detecting different test materials on the same snare.

Therefore, Applicant's present claimed invention is not obvious in view of the cited references independently or in combination.

Accordingly, Applicants request withdrawal of all rejections under the judicially created doctrine of obviousness-type double patenting.

3. Response to the Rejections of Claims 1-2, 6-9, 14-15 and 18 Based Upon 35 U.S.C. §102(e)

Claims 1-2, 6-9, 14-15 and 18 stand rejected under 35 USC §102(e) as being anticipated by Muller et al (US 5,804,384). This rejection is respectfully traversed by the amendment.

Claims 1 and 14 are independent claims. Claims 2 and 6-9 are dependent claims of Claim 1, Claims 15 and 18 are dependent claims of Claim 14, respectively.

For there to be anticipation under 35 U.S.C. §102, "each and every element" of the claimed invention must be found either expressly or inherently described in a single prior art reference. *Verdegaal Bros vs. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) and references cited therein. See also *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565, 1581, 230 USPQ 81, 84 (Fed. Cir. 1986) ("Absence from the reference of any claimed element negates anticipation."); *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). As pointed out by the court, "[t]he identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). An anticipating reference

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must describe the patented subject matter with sufficient clarity and detail to establish that the subject matter existed and that its existence was recognized by persons of ordinary skill in the field of the invention. *ATD Corp V. Lydall, Inc.*, 159 F.3d 534, 545, 48 USPQ 2d 1321, 1328 (Fed. Cir. 1998). See also *In re Spada*, 911 F.2d 705, 708, 15 USPQ 2d 1655, 1657 (Fed. Cir. 1990).

As positively recited in the amended independent Claims 1 and 14, Applicant's claimed method include detection of multiple test materials by having at least two target capture materials on the same snare, binding multiple test materials on the same snare, adding different probes sequentially on the same test snare, and detecting different test materials sequentially on the same test snare.

Applicant submits that the claimed subject matter is not disclosed, taught or suggested by the art of record. More specifically, Muller et al fail to teach Applicant's claimed method which has the first and second probes bonding to the same snare, and detects the first and the second test materials on the same snare.

On the contrary, Muller et al teach a method that adds a sample into a tube which contains a linear series of binding elements, each linked to a distinct binding factor to which a specific analyte binds, captures an analyte on a specific binding element, and detects a plurality of different analytes on different binding elements (Column 21, lines 45-50; and Column 18, lines 52-62 and Figs. 4A and 4B). Muller et al specifically teach, as an advantage of their invention, that due to the physical separation of the different specific detector probes bounded to different binding elements of the device, a single label can be used on multiple, distinct detector probes in the same assay (Column 11, lines 27-30).

It is apparent Muller et al's method relied on the physical separation of different binding elements for detection of multiple analytes, each bound to one binding element, is fundamentally different from Applicant's claimed method of binding and detecting multiple analytes on the same snare. Therefore, the reference fails to anticipate or suggest Applicant's claimed method.

Accordingly, Applicant respectfully requests withdrawal of the rejection of

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Claims 1 and 14 based upon 35 U.S.C. §102(e).

With regard to Claims 2, 6-9, 15 and 18, as described above, these claims are dependent upon independent Claims 1 and 14. Under the principles of 35 U.S.C. §112, 4th paragraph, all of the limitations of each independent claim are recited in its respective dependent claims. As described above, independent Claims 1 and 14 are not anticipated by the prior art of record, as such Claims 2, 6-9, 15 and 18 are submitted as being allowable over the art of record.

In view of the above, Applicant respectfully requests withdrawal of the rejection of Claims 1-2, 6-9, 14-15 and 18 based upon 35 U.S.C. §102(e).

4. Response to the Rejections of Claims 3-5 and 16-17 Based Upon 35 U.S.C. §103(a)

Claims 3-5 and 16-17, stand rejected under 35 USC §103(a) as being unpatentable over Muller et al (US 5,804,384) in view of Lee et al (US 5,672,475). This rejection is respectfully traversed by the amendment.

Claims 3-5 and 16-17 are dependent claims of Claims 1 and 14, respectively. Applicants' claimed invention defined by Claims 1 and 14 has been described above. Claims 3-5 and 16-17 further define the chemical labels are chemiluminescence labels, more specifically acridinium dye.

A determination under 25 U.S.C. §103 is whether the claimed invention as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made. *In re Mayne*, 104 F.3d 1339, 1341, 41 USPQ 2d 1451, 1453 (Fed. Cir. 1997). An obviousness determination is based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and prior art; and (4) the objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966), see also *Robotc Vision Sys., Inc. v. View Eng'g Inc.*, 189 F.3d 1370 1376, 51 USPQ 2d 1948, 1953 (Fed. Cir. 1999).

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In line with this standard, case law provides that "the consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in the light of the prior art." *In re Dow Chem.*, 837 F.2d 469, 473, 5 USPQ 2d 1529, 1531 (Fed. Cir. 1988). The first requirement is that a showing of a suggestion, teaching or motivation to combine the prior art references is an "essential evidentiary component of an obviousness holding." *C.R. Bard, Inc. v. M3 Sys. Inc.*, 157 F.3d 1340, 1352, 48 USPQ 2d 1225, 1232 (Fed. Cir. 1998). This showing must be clear and particular, and broad conclusory statements about the teaching of multiple references, standing alone, are not "evidence." *In re Dembiczak*, 175, F.3d 994, 1000, 50 USPQ 2d 1614, 1617. The second requirement is that the ultimate determination of obviousness must be based on a reasonable expectation of success. *In re O'Farrell*, 853 F.2d 894, 903-904, 7 USPQ 2d 1673, 1681 (Fed. Cir. 1988); see also *In re Longi*, 759 F.2d 887, 897, 225 USPQ 645, 651-52 (Fed. Cir. 1985). The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. *In re Fritch*, 972 F.2d 1260, 1265, 23 USPQ 2d 1780, 1783-84 (Fed. Cir. 1992).

The examiner has the burden of establishing a prima facie case of obviousness. *In re Deuel*, 51 F.3d 1552, 1557, 34 USPQ 2d 1210, 1214 (Fed. Cir. 1995). The burden to rebut a rejection of obviousness does not arise until a prima facie case has been established. *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ 2d 1955, 1957 (Fed. Cir. 1993). Only if the burden of the establishing prima facie case is met does the burden of coming forward with rebuttal argument or evidence shift to the application. *In re Deuel*, 51 F.3d 1552, 1557, 34 USPQ 2d 1210, 1214 (Fed. Cir. 1995), see also *Ex parte Obukowicz*, 27 USPQ 2d 1063, 1065 (B.P.A.I. 1992).

Applicant submits that nothing in the art of record teaches or suggests the subject matter positively recited in independent Claims 1 and 14. As recited in Claims 1 and 14, Applicant's method binds different test materials on the same test

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snare and detects different test materials on the same test snare.

Muller et al's teaching has been discussed previously. Applicant specifically points out that Muller et al teaches away from Applicant's claimed method of detecting multiple test materials in a sample. Because Muller et al's method binds multiple analytes on to different binding elements which are physically separated, and detects these analytes on different binding elements.

The deficiencies of Muller et al's reference are not overcome by Lee et al. Lee et al fails to teach Applicant's claimed method of binding and detecting multiple test materials on the same test snare.

Based on the prior art's teachings, one ordinary skilled in the art would not be motivated to apply Lee et al's acridinium dye to Muller et al's detection probe to obtain Applicant's claimed method. Even if one does, in the manner suggested by the Examiner, one could only end up detecting different test materials on Muller et al's physically separated different binding elements, which is fundamentally different from Applicant's method of detecting multiple test materials on the same test snare.

Therefore, Applicants maintain that Applicants' claimed invention defined by independent Claims 1 and 14 are not obvious in view of prior art of the record.

With regard to Claims 3-5 and 16-17, as described above, these claims are dependent upon independent Claims 1 and 14. Under the principles of 35 U.S.C. §112, 4th paragraph, all of the limitations of each independent claim are recited in its respective dependent claims. As described above, independent Claims 1 and 14 are not anticipated by the prior art of record, as such Claims 3-5 and 16-17 are submitted as being allowable over the art of record.

Accordingly, Applicant respectfully requests withdrawal of the rejection of Claims 3-5 and 16-17 based upon 35 U.S.C. §103(a).

5. Response to the Objections of Claims 10-13, 19-23, and 24-25

Applicant appreciates the Examiner's indication of allowable subject matters

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defined by Claims 10-13, 19-23, and 24-25.

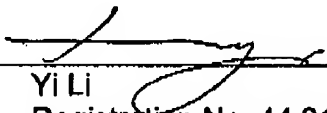
As discussed above, independent Claims 1 and 14 are not anticipated, or rendered obvious by the prior art of record, as such dependent Claims 10-13 and 19-23, are submitted as being allowable over the art of record.

Furthermore, Applicant respectfully points out that in the instant Office Action, the Examiner indicates that Claim 24 is a dependent claim. In fact, Claim 24 is an independent claim and Claim 25 is dependent on Claim 24. However, Claim 24 recites all claim limitations of Claims 14 and 19. Therefore, based on the allowability stated in the Summary of the instant Office Action, Applicant understands that the Claim 24, as filed, is allowable over the prior art of record. Accordingly, Applicant respectfully requests allowance of Claims 24-25.

It is respectfully submitted that Claims 1-24, the pending claims, are now in condition for allowance and such action is respectfully requested.

Applicant's Agent respectfully requests direct telephone communication from the Examiner with a view toward any further action deemed necessary to place the application in final condition for allowance.

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